James E. McLaughlin, Ph. D. Program Manager Toxicology Department Rohm and Haas Chemicals, LLC 727 Norristown Road P.O. Box 0904 Spring House, PA 19477-0904

Dear Dr. McLaughlin:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the test plan and robust summaries for 2,2,4-trimethyl-2-pentanamine (Primene™TOA; CAS No. 107-45-9) dated August 1, 2006. EPA posted the submission on the ChemRTK HPV Challenge Program Web site on September 7, 2006.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

- (1) For the physicochemical and environmental fate endpoints, EPA agrees with the test plan.
- (2) For the human health endpoints, EPA agrees with the plan to provide data for the repeated-dose/reproductive/developmental toxicity endpoints according to the combined screening test OECD TG 422. For the chromosomal aberrations endpoint, although the submitter proposed to conduct an *in vivo* micronucleus assay according to OECD Guideline 474, EPA encourages conducting an *in vitro* genotoxicity study (OECD TG 473) rather than an *in vivo* study unless the properties of the chemical indicate otherwise.
 - (3) For the ecotoxicity endpoints, EPA agrees with the test plan.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that Rohm and Haas advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send electronic revisions or comments to the following e-mail address: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact me at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Mark W. Townsend, Chief HPV Chemicals Branch

Enclosure

cc: O. Hernandez N. Patel J. Willis